

# Notice of Allowability

Application No.

09/980,361

Examiner

Jeffrey T Barton

Applicant(s)

LI ET AL.

Art Unit

1753

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to \_\_\_\_\_.
2. ☒ The allowed claim(s) is/are 1-27.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All b) ☐ Some\* c) ☐ None of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date 20040622.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 20040622 8 July 2004
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other See Continuation Sheet.

Continuation of Attachment(s) 9. Other: English abstract and machine translation of Japanese patent, Anal. Chem. reference.

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given by Mr. Lawrence Ginsberg in a telephone interview on 08 July 2004.

The application has been amended as follows:

**In the drawings:**

- a. Please amend Figures 1A and 1B to include a legend indicating that they illustrate prior art.
- b. Please remove reference labels 22, 24, 28, and G from Figure 2A; 56 from Figure 2B; H from Figure 4; and 92 from Figure 5.

**In the claims:**

- a. In claim 2 at line 6, please delete the word "channel" and insert the word --channels-- after the word "separation".
- b. In claim 2 at line 10, please delete the phrase "a plurality of sensor reservoirs" and insert the phrase --at least one sensor reservoir provided

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for each said conductive element, said sensor reservoir-- at the beginning of the line.

- c. In claim 2 at line 11, please delete the phrase "each connected to one of" and insert the phrase --and being connected to-- after the word "medium".
- d. In claim 2 at line 12, please delete the word "channel" and insert the word --channel-- after the word "separation".
- e. In claim 2 at line 15, please delete the word "end" and insert the word --ends-- after the word "inlet".
- f. In claim 2 at line 16, please delete the word "channel" and insert the phrase --separation channels-- after the word "said".
- g. In claim 2 at line 20, please delete the word "electrode" and insert the word --electrodes-- after the word "sensing".
- h. In claim 2 at line 22, please delete the word "channel" and insert the word --channels-- after the word "separation".
- i. In claim 2 at line 23, please delete the word "element" and insert the phrase --conductive element-- after the word "said".
- j. In claim 3 at line 11, please delete the word "to" and insert the word --and-- after the phrase "inlet end".
- k. In claim 11 at line 2, please delete the word "second" after the word "a".
- l. In claim 12 at line 5, please delete the word "potential" and insert the phrase --potential difference-- at the beginning of the line.

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- m. In claim 13 at line 6, please insert the word --signal-- after the word "difference".
- n. In claim 13 at line 13, please insert the word --difference-- after the word "separation".
- o. In claim 23 at line 4, please delete the word "of" and insert the word --being-- after the word "wall".
- p. In claim 25 at line 3, please delete the word "wall" and insert the word --element-- after the word "conductive".
- q. In claim 26 at line 4, please delete the word "wall" and insert the word --element-- after the word "conductive".

2. The following is an examiner's statement of reasons for allowance:

The instant invention is distinguished over the prior art of record in that it detects analytes in a separation channel by measuring changes in the potential gradient between the capillary outlet and a conductive element provided on the separation channel near the outlet. The prior art of record neither teaches nor suggests the combination of limitations recited in the instant claims.

In Japanese Patent No. JP 11108890 A, Chiba et al teach the placement of closely-spaced electrodes along the separation channel and in contact with the fluid and the use of these electrodes to detect the potential gradient present in the channel. However, they do not disclose that one of the electrodes could be located at the outlet of the capillary.

Other electrophoretic systems that incorporate conductive elements (e.g. electrodes or breaks/frits with electrolyte) passing through capillary walls are disclosed in U.S. Patent Nos. RE 35,102 (Zare et al.), 5,169,510 (Lunte et al.), 5,580,435 (Kovacs), 5,441,613 (McCormick et al.), and 5,906,723 (Mathies et al.); and by Wallingford et al (Anal. Chem. reference). However, the prior art systems do not share principles of operation with the instant invention. Zare et al, Lunte et al, McCormick et al, and Wallingford et al locate the ground electrode such that it communicates with the conductive element upstream from the capillary outlet and allows for downstream detection outside the influence of the driving voltage. Mathies et al and Kovacs disclose electrodes that pass through the capillary walls, but they are not used to detect potential gradients and neither detection electrode is positioned at the capillary outlet. These modes of operation are distinct from those of the instant claims.

Thus, it would not have been obvious to one having ordinary skill in the art at the time of the invention to have modified the systems of prior art to detect potential gradients between a position within the capillary and the capillary outlet.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

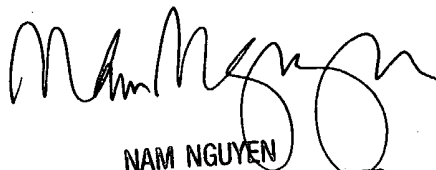
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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB  
July 9, 2004

  
NAM NGUYEN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700